Overview of the Quality System Regulation for Medical Devices

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Background

- Effective June 1, 1997, replacing the 1978 GMP for medical devices
- Preamble to the 1997 regulation - VERY Important
- Requirements are not prescriptive
- Provides framework of basic requirements for manufacturers to follow

Bottom line …
It's your Quality System!

A manufacturer must develop a QS commensurate with:

- **risk presented by the device**

Bottom line …
It's your Quality System!

A manufacturer must develop a QS commensurate with:

- **complexity of device and manufacturing processes**
- **size and complexity of manufacturing facility**

Quality Paradigms

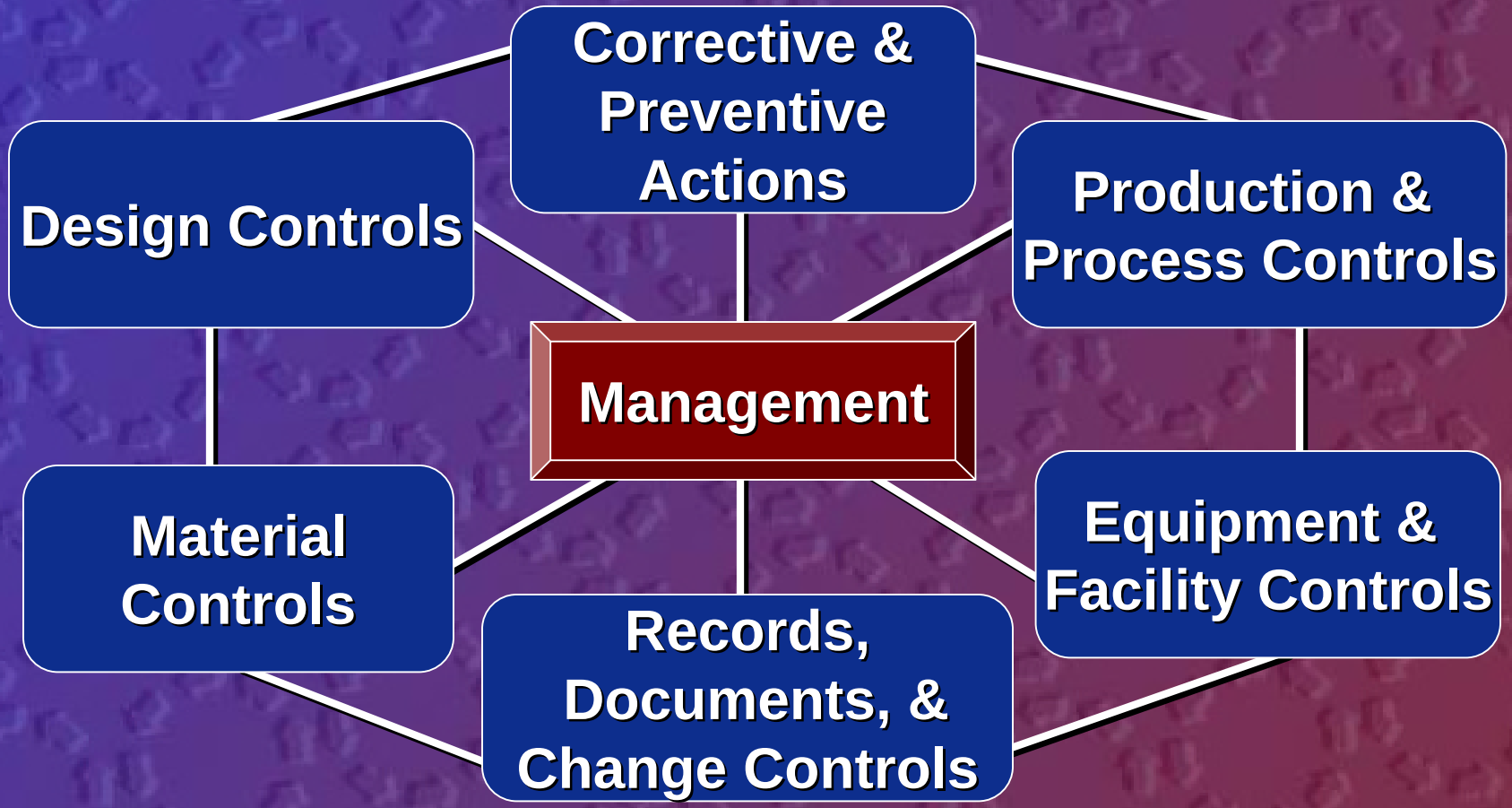
- **Quality Control -**
  Test/inspect components, finished products vs approved specifications

- **Quality Assurance -**
  Manufacture quality into products

Quality Paradigms

- **Quality System -**
  Design and manufacture quality into products, and includes specific CAPA requirements

Quality System



“Establish” 21CFR 820.3(k)

- Define
- Document
- Implement (Do)

Remanufacturer 21 CFR 820.3(w)

- Any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or **intended use**.

Management Controls

- Appoint a management representative
- Conduct management reviews
- Ultimately responsible for the entire Quality System

Design Controls

- Class II
- Class III
- Class I per 21CFR 820.30(a)(2)

Design Control Impact

- **Fact: On June 1, 1997 the Quality System Regulation became effective**

Design Controls

- Design Controls DO apply to products being reused
- Must back engineer the devices design
- Must design the process to meet device specifications

Types of “Product”

- Medical Devices that were marketed prior to June 1, 1997 and **have not** changed
- Medical Devices that were marketed prior to June 1, 1997 and **have** changed

Types of “Product”

- Class II, Class III and applicable Class I medical devices that were in development prior to **and** after June 1, 1997

Design Controls - Reuse

- Since the remanufacturer will be unaware of any changes in the devices design specifications - every device that is remanufactured must go through design controls, as well as the process used to remanufacture

What are my obligations regarding my medical devices that were marketed prior to June 1, 1997 and have changed?

"When changes are made to new or existing designs, the design controls of §820.30 must be followed to ensure that the changes are appropriate and that the device will continue to perform as intended."

Preamble p. 52616, response to comment 64

Anything else?

“Procedures must ensure that after the design requirements are established and approved, changes to the design, both pre-production and post-production are also reviewed, validated (or verified where appropriate), and approved.”

Anything else?

“The records of these changes create a history of the evolution of the design, which can be invaluable for failure investigation and for facilitating the design of future similar products.”

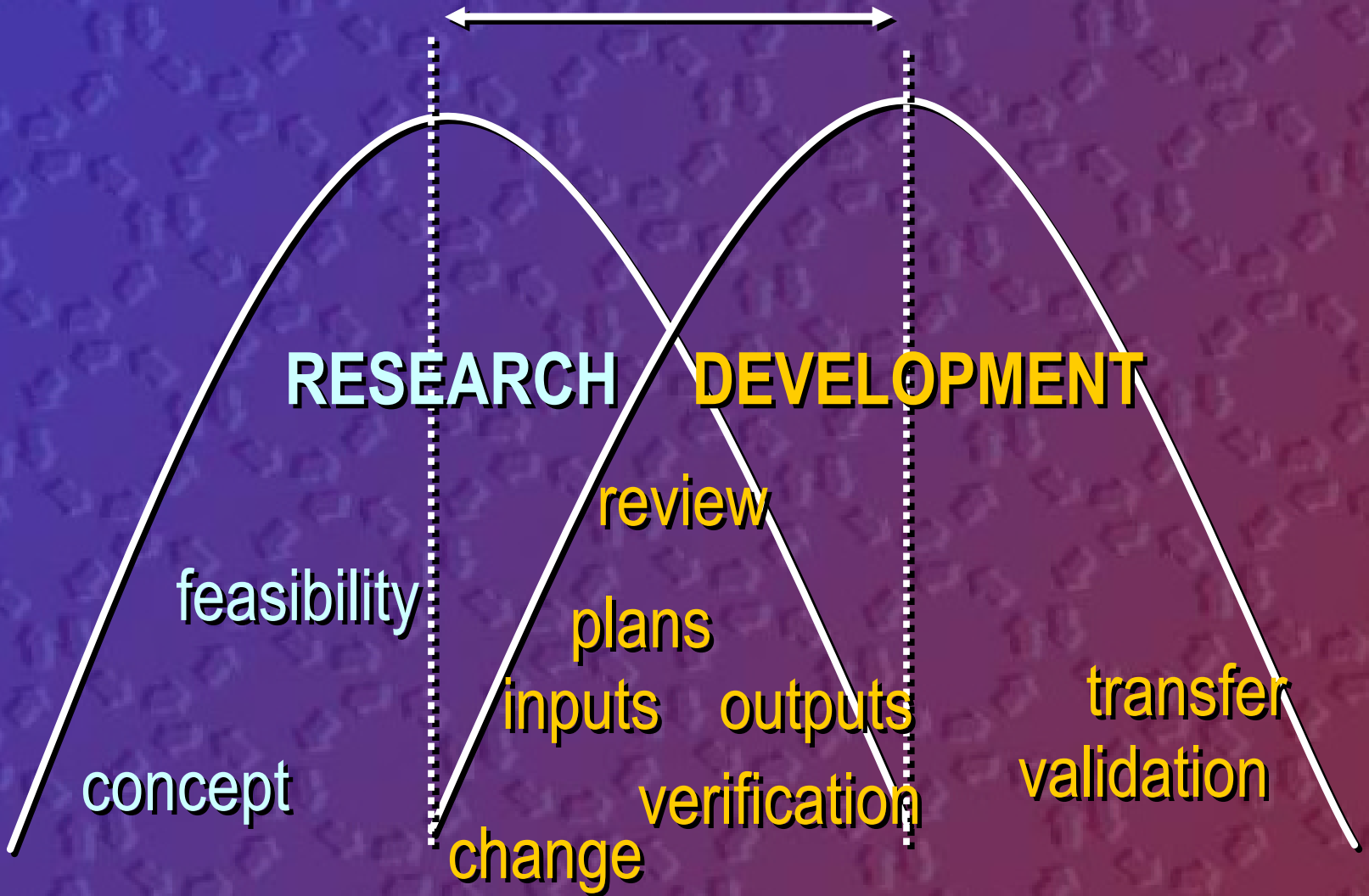
Preamble p. 52621, response to comment 87

How much is enough?

“The evaluation and documentation should be in direct proportion to the significance of the change.”

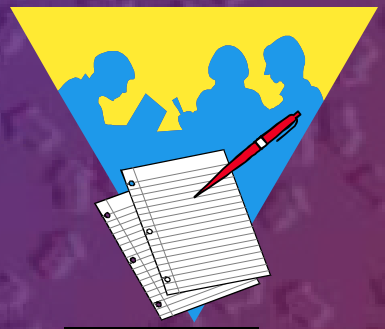
Preamble p. 52621, response to comment 87

Application of Design Controls



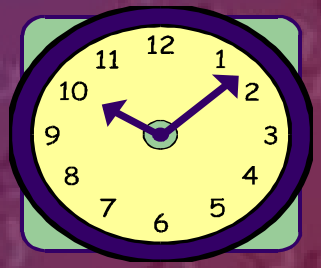
Design Reviews

- Purpose



- Participants

- Timing



Design Verification and Design Validation

Design *Verification*…
Is the product specifications being met and can I prove it?
Design *Validation*…
Is the product meeting user needs and intended uses for all specifications, even after remanufacturing and can I prove it?

Design Validation and Process Validation

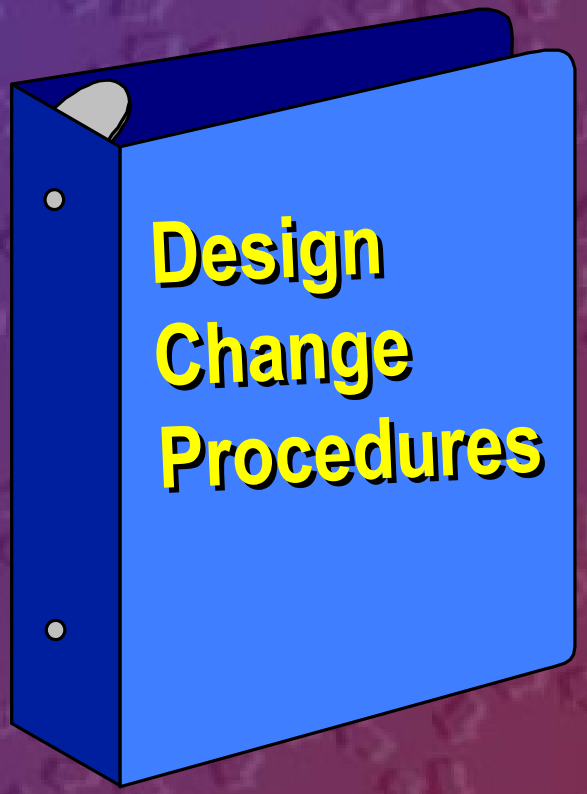
***Design* Validation…**

Is the product meeting user needs and intended uses and can I prove it?

***Process* Validation…**

Does the process consistently produce a result or product meeting predetermined specifications and can I prove it?

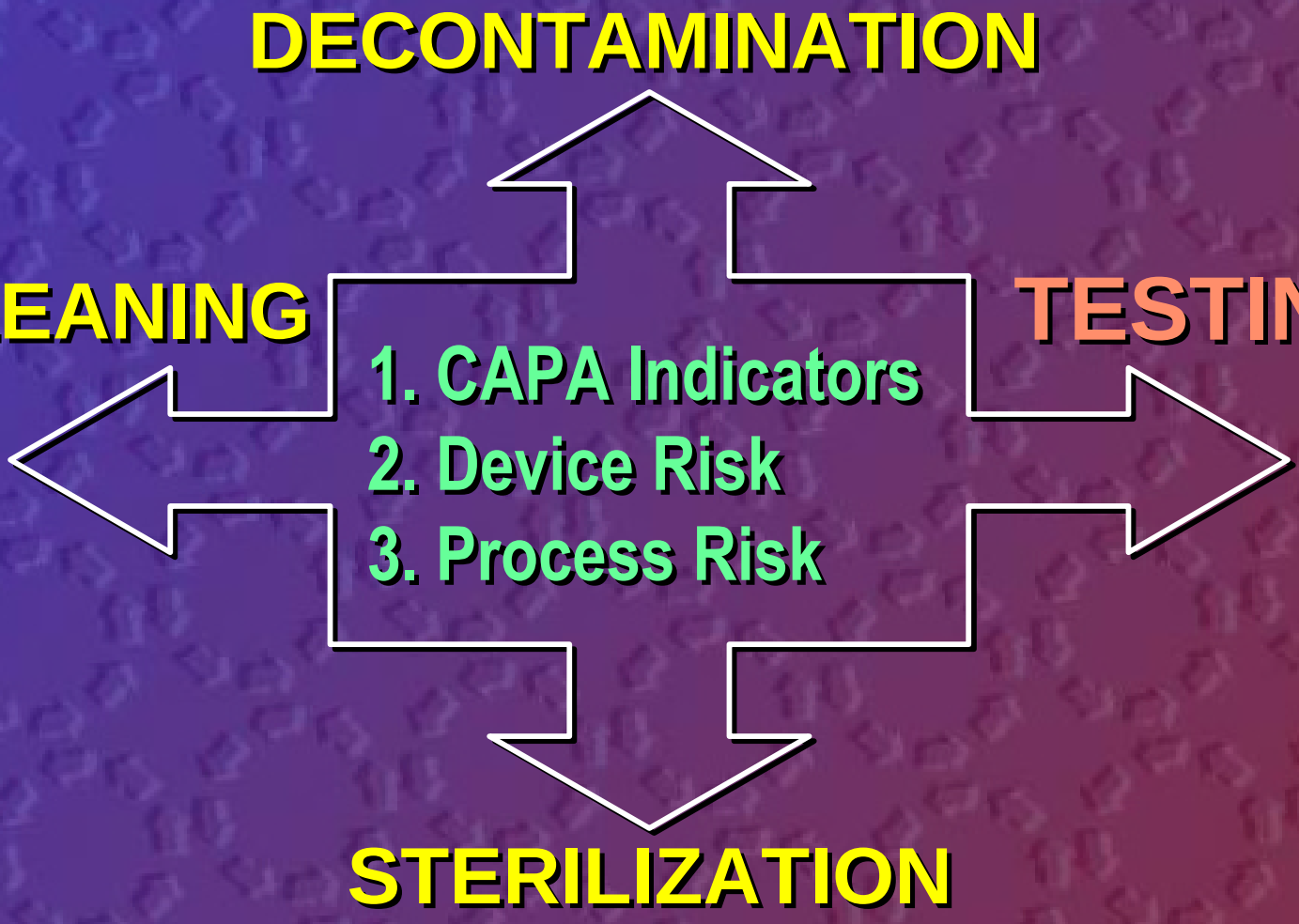
Define and Document Design Change Procedures



Design Controls Helpful Hints...

- Understand the jargon
- Use the results of Risk Analysis and management tools throughout the design control process

Production & Process Controls



Plus...

- Purchasing
- Acceptance
- Buildings & Equip.
- Calibration
- Personnel
- Statistical Tech.’s
- Others

Automated Processes

- Requirements
- Validation Protocol
- Validation Activities
- Validation Results
- Change Controls

Is The Process Operating Within Specified Limits?

If NO, then review…

- Nonconforming Product Controls
- Resulting CAPA's
- Equipment Adj., Cal. & Maint.
- Validation (where required)

Production and Process Controls

- Validate processes if results cannot be fully verified by subsequent inspection and test
- Validate software used in manufacturing and in the quality system
- Control and monitor manufacturing processes

Corrective and Preventive Action

- Collect and analyze data to identify nonconforming product and other quality problems
- Investigate cause
- Identify and implement corrective and preventive action

Corrective and Preventive Action

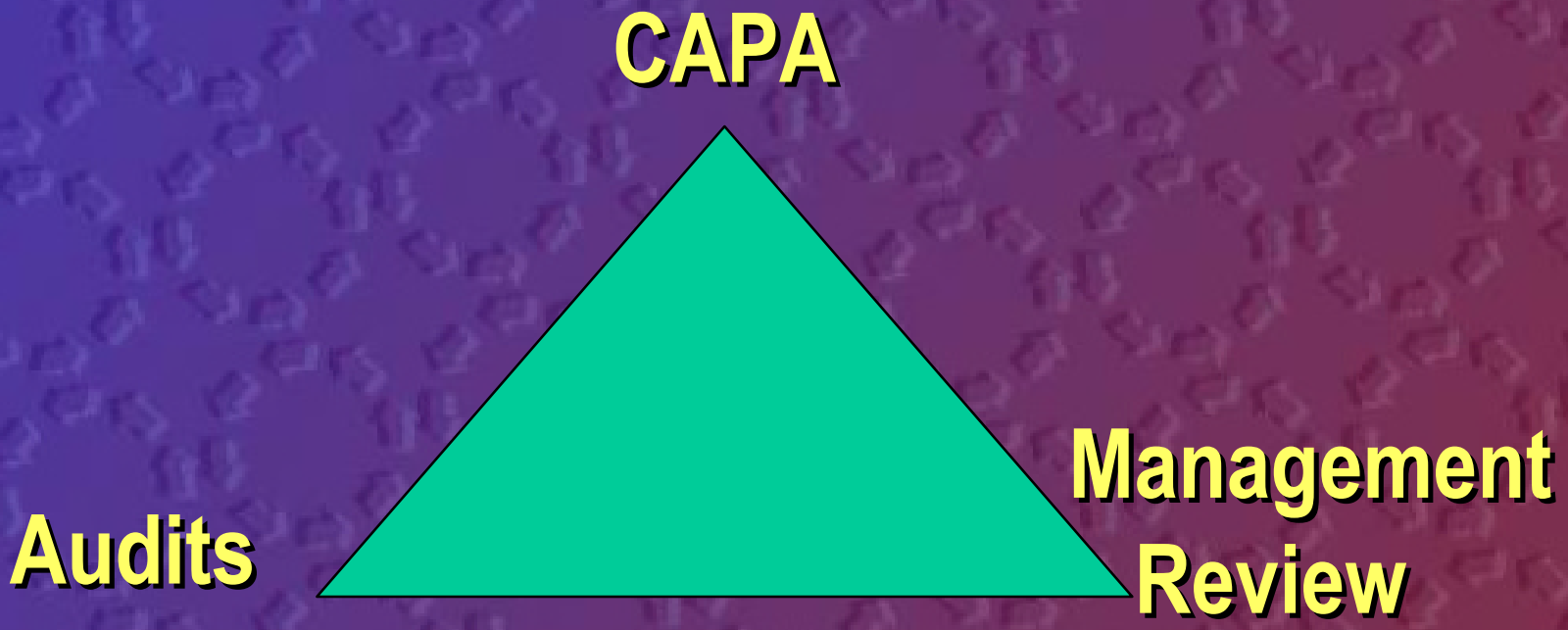
- Verify or validate effectiveness
- Communicate information about quality problems to staff
- Forward information for management review

Have the CAPA Requirements Been “established”?

- Defined
- Documented
- Implemented

§820.3(k)

Staying informed …



Who is responsible...

"FDA emphasizes that it is always management's responsibility to ensure that all nonconformity issues are handled appropriately."

Comment 165

Correction vs. Corrective Action

"Correction" **refers to repair, rework, or adjustment and relates to the disposition of an existing nonconformity**

"Corrective action" **relates to the elimination of the causes of an existing nonconformity**

"Healthy" CAPA subsystem procedures include provisions to ...

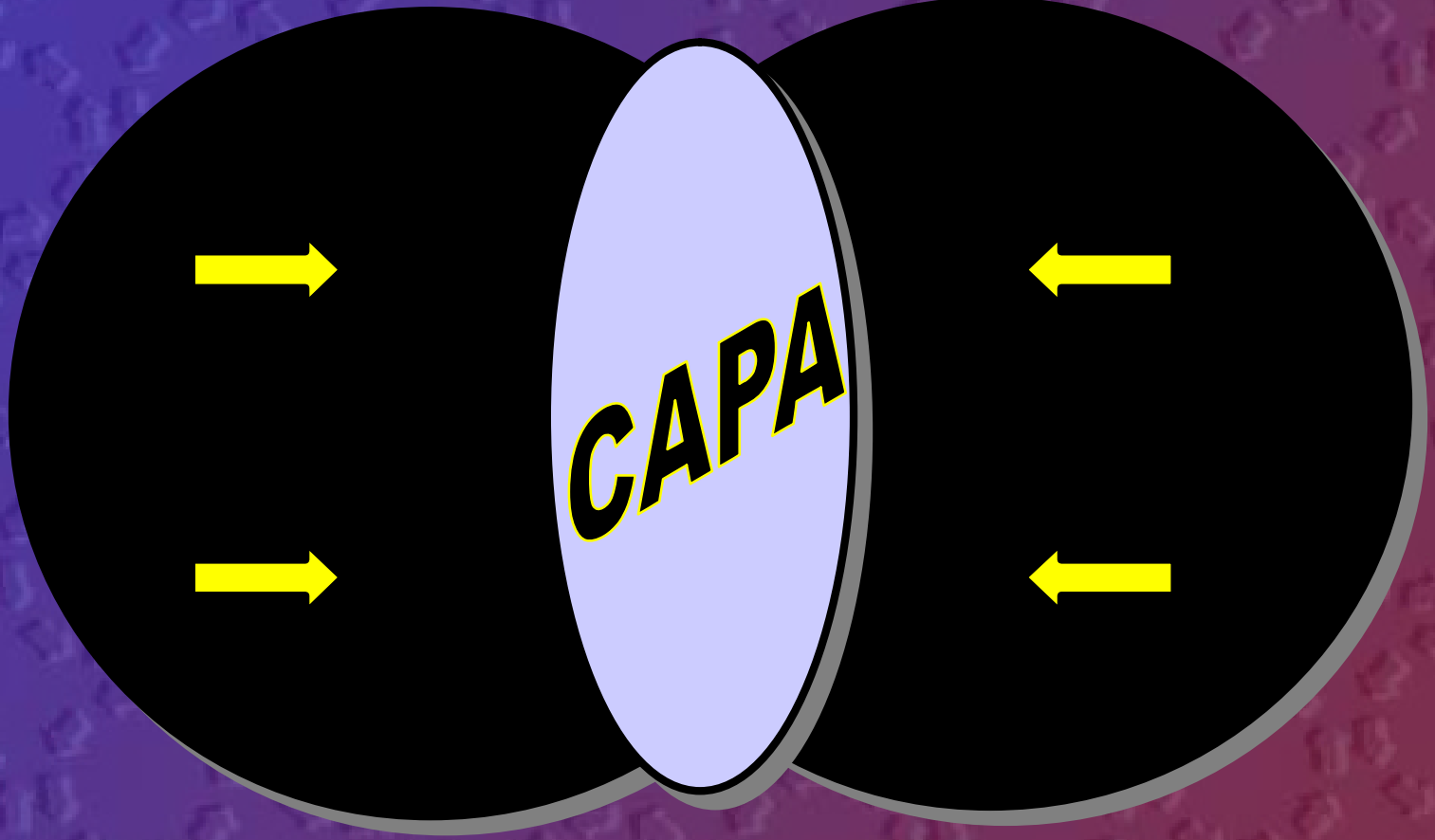
1. Identify and correct **existing** nonconforming product or other quality problems ("Correction");

2. Identify and eliminate the **causes** of existing nonconforming product and other quality problems ("Corrective Action"); and,

"Healthy" CAPA subsystem procedures include provisions to ...

3. Identify and eliminate the causes of **potential** nonconforming product and other quality problems ("Preventive Action")

Quality Data Sources



Internal Data Sources

- Acceptance Activities (Inspection and Test Data)
  - component, in-process and final test
  - scrap/yield

Internal Data Sources

- Nonconforming product
  - scrap, rework, UAI
- Process monitoring
  - process control data, control charts, SPC

Internal Data Sources

- Equipment monitoring
  - calibration, maintenance
- Device History Records
- Change Control Records

Internal Data Sources

- Internal Audits
- 3rd Party Audits
  - ISO
  - FDA
- Supplier Audits
- Management Review Results

External Data Sources

- Complaints & MDR's
- Servicing
  - warranty, non-warranty
  - field service reports
  - returns
- Recalls
- Legal Claims

Seeking Quality Data

- Solicit feedback to support continuous improvement
  - Customer Feedback
  - Employee Feedback
  - ISO 9001:2000
  - Principles of Quality Management

CAPA Program

- PRO active

  vs.

- RE active

CAPA Program

- Single or multiple CAPA systems
  - internal audits
  - supplier audits
  - inspection and test data
  - nonconforming product
  - complaints and servicing
- ALL must meet 820.100

CAPA Program

- Identify data sources
- Document the problem
- Establish a priority system
  - consider impact / risks and select items with major impact
  - proceed to items with less impact

CAPA Program

- Analyze the problem
  - root cause analysis
- Develop an action plan
  - consider impact and need for…
  - short term corrective action
  - long term corrective action

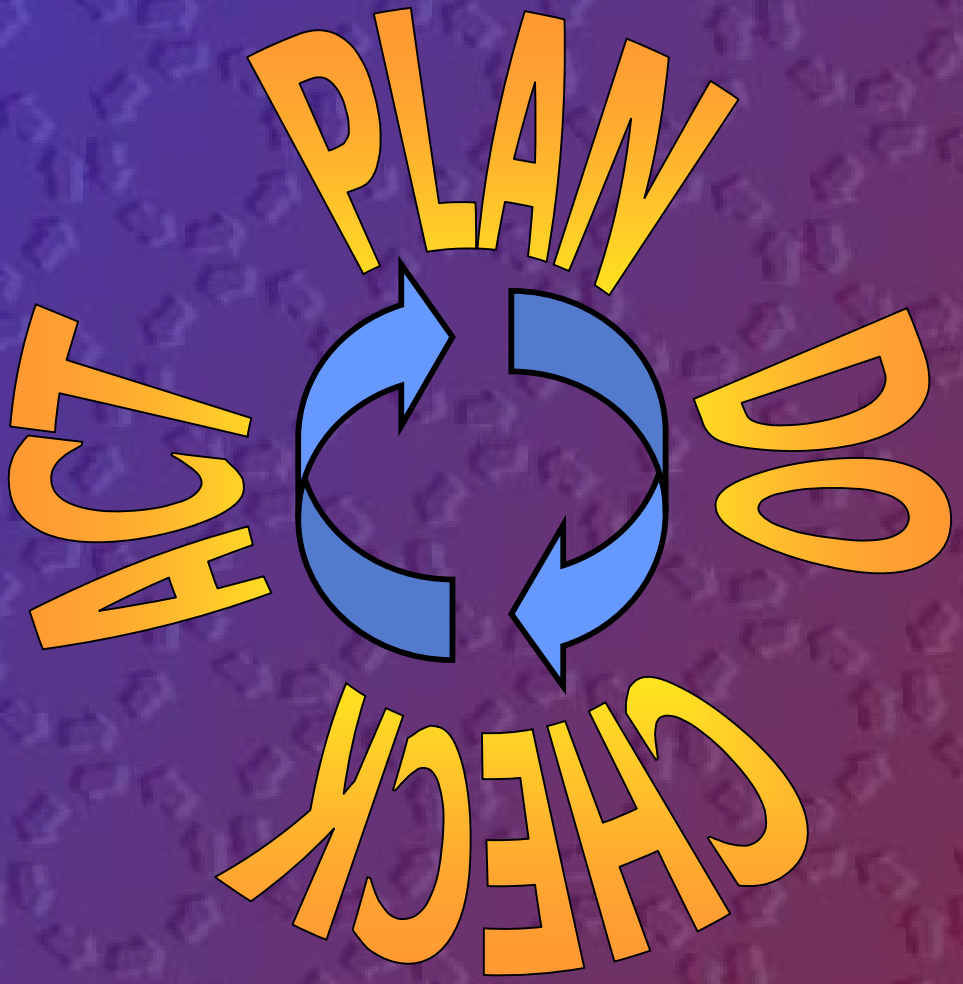
CAPA Program

- Verification and Validation
  - analysis of data may lead to more than one solution, assure solution is appropriate
- Implementation
  - tracking for on-time completion

CAPA Program

- Documentation and follow-up
  - corrective action effective
  - adverse effect on product
  - records
- Communicate changes
  - to those directly responsible
  - management review

Close the loop...



For Further Information

- General
  - www.fda.gov/cdrh/index.html
- Quality System Regulation
  - www.fda.gov/cdrh/fr1007ap.pdf
- QSIT Guide
  - www.fda.gov/ora/inspect_ref/igs/qsit/qsitguide.pdf